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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,957	01/11/2001	Robert N. Hanson	ZAA-011.01	9648

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FOLEY HOAG LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02110-2600

EXAMINER	
BAKER, MAURIE GARCIA	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 07/30/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/758,957	Hanson et al
Examiner	**Art Unit**
Maurie Garcia Baker, Ph. D.	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 7, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-54* is/are pending in the applica

4a) Of the above, claim(s) *1-14, 21, 28-42, and 44-54* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *15-20, 22-27, and 43* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The Response filed May 7, 2002 (Paper No. 8) is acknowledged. No claims were amended, added or cancelled. Therefore, claims 1-54 are pending.

Election/Restriction

2. Applicant's election with traverse of Group II (claims 15-42 and 43 (in part)) is acknowledged as well as the election of species. The traversal is addressed below.

3. Applicants traverse the Restriction Requirement with respect to the separation of the claims of Group II from Group I and state that combined search and examination would not create an undue burden. However, the examiner maintains that the inventions are distinct because they represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter.

4. As stated previously, each of the polypharmacophores of the general formulas **(I)/(IA)** and **(II)/(IIA)/(III)/(IIIA)** are deemed to have a chemically different structure. If applicant declares ***equivalency*** between the general formulas **(I)/(IA)** and **(II)/(IIA)/(III)/(IIIA)**, the groups would be examined together. Since no assertion has been made, the requirement is maintained.

5. Again, as stated in the Restriction Requirement, there is no expectation that the searches of these two groups would be coextensive. Therefore, this does create an undue search burden. The requirement is still deemed proper and is therefore made FINAL.

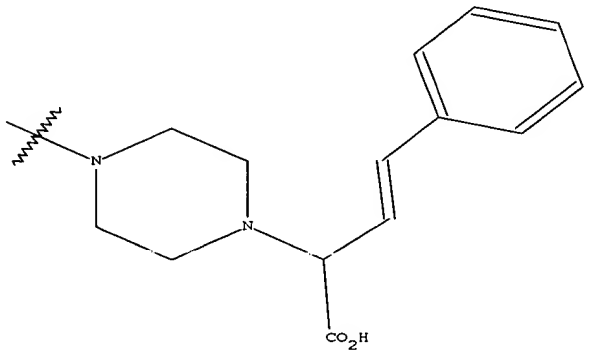
6. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between elected Group II and Groups III – X, the election has been treated as an election without traverse (MPEP § 818.03(a)) with respect to these groups.

7. Thus, claims 1-14 and 43 (in part) (Group I) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

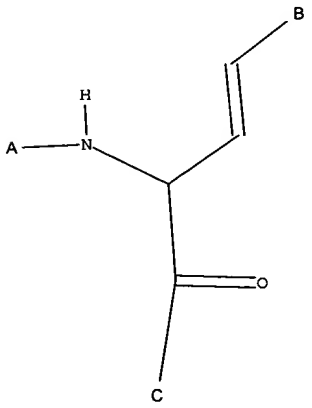
8. Claims 44-54 (Groups III – X) are also withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Election was made **without** traverse in Paper No. 8 with respect to these claims (see paragraph 6 above).

9. Applicant has not set forth the claims reading on the elected species. However, claims 21, 28, 35 and 42 are specifically drawn to modifiers, and a compound with *no modifiers* was elected. Thus, these claims do not read on the elected species.

10. Moreover, ***all*** of claims 29-42 do not read on the elected species for the following reason. The elected species (Response, page 2, top) is the following structure (shown in part):



However, claims 29-42 are drawn to a "polypharmacophore" comprising the formula (III) {and similarly (IIIA)}:



This structure contains a secondary nitrogen, while the elected species contains a tertiary nitrogen. There is no choice for the above "A" group that would result in the elected species since the nitrogen of the elected species has three carbons attached thereto, while the compounds of formula (III) {and similarly (IIIA)} contain a nitrogen that has ***at most*** only two carbons attached thereto. Thus, claims 29-42 ***do not*** read on the elected species.

11. For the above reasons, claims 21, 28 and 29-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic or linking claim.

12. Therefore, claims 15-20, 22-27 and 43 (in part) are examined on the merits in this action.

13. Applicant's specifically elected species was searched and was not found in the prior art. Thus, the search was expanded to non-elected species which *were* found in the prior art, see rejections below. Also, see MPEP § 803.02 (emphasis added):

> On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. ***The prior art search, however, will not be extended unnecessarily to cover all nonelected species***. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

Specification

14. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (for example, on page 28, 1st paragraph). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

15. Claim 43 is objected to because it depends from claims in a non-elected group (claims 1 and 8 from non-elected Group I). Correction is respectfully requested.

16. Claim 43 is also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. The word "and" between claim numbers 29 and 36 should be "or". See MPEP § 608.01(n). Correction is respectfully requested.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 15-20, 22-27 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a

"polypharmacophore", which is made of "pharmacophores" attached to a "scaffold unit". The specification only defines a pharmacophore as an "agent capable of having a biological effect" (page 10, lines 1-2). The instant specification does not specifically define "scaffold unit". The claims contain no structural information whatsoever. There is no information on the structure of the "pharmacophores" or "scaffold unit" or sites for attachment. The only other limitation found in the claims is that the "the polypharmacophore interacts with at least two biological targets".

These "polypharmacophores" are made up of pieces (i.e. "pharmacophores") that could encompass very different moieties such as peptides and organic molecules; these pieces are attached to an undefined scaffold in an undefined way. There are a virtually unlimited number of compounds that would fall within the claimed genus and applicant's claimed scope represents only an invitation to experiment regarding possible "polypharmacophores". The instant specification only discloses **very limited** examples of the preparation and use of such "polypharmacophores".

With respect to adequate disclosure of the scope of the presently claimed generic applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding disclosure. For adequate disclosure, like enablement, requires *representative examples* which provide reasonable assurance to one skilled in the art that the compounds falling

within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention.* See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and University *of California v. Eli Lilly and Co* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure.

Therefore it is deemed that the disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that the structural features of the exemplified compounds do not constitute support for the claimed genus or a substantial portion thereof.

19. Claims 15-20, 22-27 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically exemplified "polypharmacophores", does not reasonably provide enablement for **any** "polypharmacophore" as set forth in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention when the "polypharmacophore" is one of those that are specifically

exemplified; however, there is insufficient guidance as to how to make/use **any** "polypharmacophores" as set forth in the claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the level of one of ordinary skill;
(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims are drawn to a "polypharmacophore", which is made of "pharmacophores" attached to a "scaffold unit". The specification only defines a pharmacophore as an "agent capable of having a biological effect" (page 10, lines 1-2). The instant specification does not specifically define "scaffold unit". The claims contain no structural information whatsoever. There is no information on the structure of the "pharmacophores" or "scaffold unit" or sites for attachment. The only other limitation found in the claims is that the "the polypharmacophore interacts with at least two biological targets". Such represents extremely broad scope.

(3 and 5) The state of the prior art and the level of predictability in the art: Compounds that contain multiple "pharmacophores" were known in the art at the

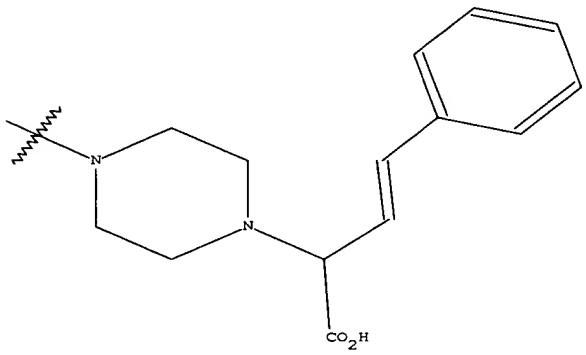
time of filing (see art rejections below); however, only limited numbers of such compounds were known and the specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of *any* polypharmacophore made up of any pharmacophores where the only defined function thereof is an "agent capable of having a biological effect". The structures of possible variants are extremely diverse and one of ordinary skill would not be able to predict their structures. The limitation that the pharmacophores are linked together (via a scaffold) adds to the unpredictability because pharmacophores of various structures would require completely different linkage strategies.

One of ordinary skill could not guess, *a priori*, how to make and use **any** such polypharmacophore as one could not necessarily predict the linkage site and linkage structure of any pharmacophore to any scaffold in the absence of guidance without undue experimentation. Applicant's claimed scope of "polypharmacophores" represents only an invitation to experiment regarding linking possible pharmacophores with undefined linkage sites to scaffolds of undefined structure and their use.

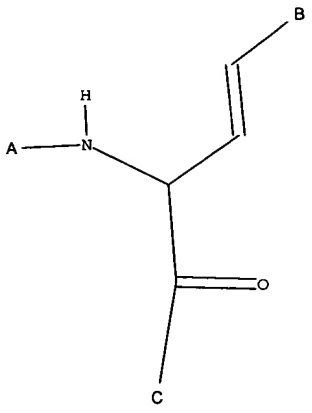
(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have only provided ***extremely limited*** examples of

the claimed "polypharmacophores". No generic strategy for determining pharmacophore structure, scaffold structure and/or linkage sites is given. Furthermore, applicant's exemplified embodiments encompass species of "polypharmacophores" that are made of pharmacophores that one of ordinary skill would not reasonably recognize (in the absence of any other teachings). For example, consider the generic claims (e.g. claim 15) as compared with the subgeneric claims (e.g. claim 29 {not under examination, non-elected species, see paragraphs 10-11}) and/or the elected species, as follows. The elected species (Response, page 2, top), is the following structure (shown in part):



When compared to the "polypharmacophore" defined in claims 29-42 comprising the formula (III) {and similarly (IIIA)} where "at least two of A, B or C comprise a pharmacophore":



it is clear that moieties such as phenyl and –OH fall within the definition of "pharmacophore". Thus, as such widely divergent structures (and partial structures) are clearly embraced by applicant's definition of "pharmacophore", the instant specification is deemed to fail to specifically identify that structure which is required for the claimed activity. This is especially true for claims 20 and 27, which recite that the "pharmacophoric units" have various activities (e.g. D-1 agonist, etc.). The instant specification fails to teach how to make and assess whether the "pharmacophoric units" that make up the claimed "polypharmacophore" have these activities.

Thus the teachings of the instant specification coupled with the examples are deemed to only provide enabling support for the specifically exemplified "polypharmacophores".

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the

full scope of the claimed compounds. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Claim Rejections - 35 USC § 112

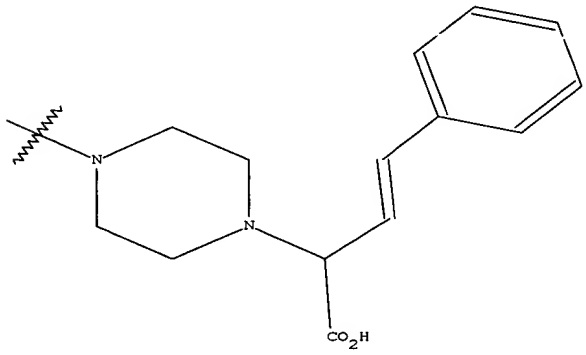
20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

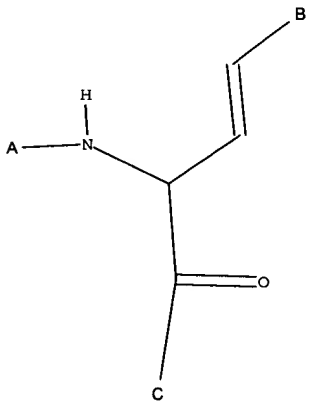
21. Claim 20 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "pharmacophoric units" in the phrase "said pharmacophoric units" is indefinite because it lacks clear antecedent basis in claims 15/22 (from which claims 20/27 depend). There is no specific recitation of "pharmacophoric units" in claims 15/22; instead, these claims recite "A, B or C comprise a ***pharmacophore***" (emphasis added).

B. The recitations in claims 20 and 27 of "wherein said pharmacophoric units are selected from the group consisting of D-1 agonist, D-2 agonist , D-3 agonist ... and dopamine transporter inhibitor" are deemed to be highly confusing and indefinite when the claims are interpreted in light of the specification. The elected species of "polypharmacophore" (Response, page 2, top), is the following structure (shown in part) and found in Figure 9:



The elected species of "pharmacophoric unit" is dopamine transporter inhibitor. However, when compared to the "polypharmacophore" defined in claims 29-42 comprising the formula (III) {and similarly (IIIA)} where "at least two of A, B or C comprise a pharmacophore":



it is clear that moieties such as phenyl and –OH fall within the definition of "pharmacophore". It is completely confusing how moieties such as these would also fit the limitation of dopamine transporter inhibitor. It is unclear how the assessment of the activity of each of the pharmacophores is determined (e.g. how is –OH determined to be a dopamine transporter inhibitor?).

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 15-20, 22-27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Gootjes (US 4,202,896; Gootjes 1) or Gootjes (US 4,265,894; Gootjes 2).

The instant claims are drawn to a "polypharmacophore", which is made of "pharmacophores" attached to a "scaffold unit". The specification only defines a pharmacophore as an "agent capable of having a biological effect" (page 10, lines 1-2). The instant specification specifically lists the elected species and several other compounds in Figures 9-12 as "certain preferred scaffolded polypharmacophores" (see *Brief Description of the Figures*, page 3).

Gootjes 1 and Gootjes 2 both disclose one of the compounds denoted in Figure 9 (top structure of the Figure) of the instant specification. Since this compound is *specifically referred to* in the instant specification as a "certain preferred scaffolded polypharmacophore", then the references read directly on the claims. See Abstract of both references; Example 9 and patented claim 7 of Gootjes 1; and Example 9 of Gootjes 2. Note that the references also disclose several other compounds that would read on those of the claims, based on the definition in the instant specification. See, for example, the propenyl containing compounds in Examples 2 and 5 of the references.

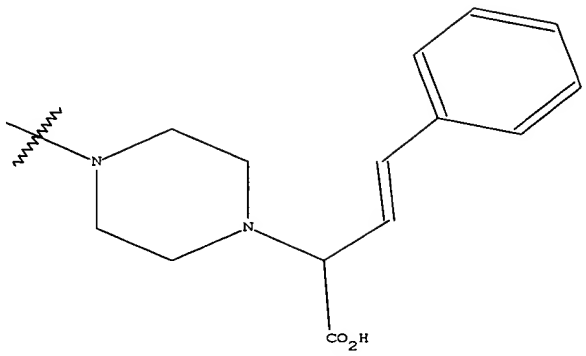
Gootjes 1 and Gootjes 2 also both disclose pharmaceutical compositions of their compounds, see Gootjes 1, patented claims 8 and 9, and Gootjes 2, patented claims 18-20. This reads on the instant claim 43.

The above compounds read on the limitations found in claims 20 and 27 as the structures of the references read directly on the claimed "polypharmacophore". Note that a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Also, note that both references disclose that their compounds have dopaminergic activity (see Gootjes 1, column 1, line 60 through column 2, line 11 and Gootjes 2, column 1, line 64 through column 2, line 15).

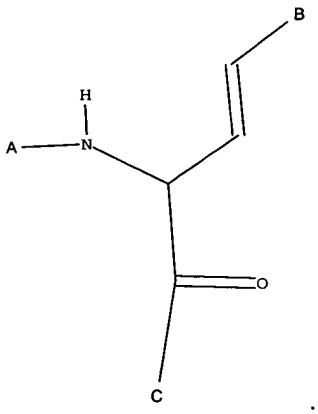
Moreover, with respect to the limitations in claims 17-19 and 24-26, the intended use recitations in these claims have not been given any patentable weight. See MPEP 2111.02: "... in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." The structures in Gootjes 1 and Gootjes 2 are deemed to be capable of performing the intended uses recited in claims 17-19 and 24-26.

24. Claims 15-20, 22-27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Moldt et al (US 5,369,113).

The instant claims are drawn to a "polypharmacophore", which is made of "pharmacophores" attached to a "scaffold unit". The specification only defines a pharmacophore as an "agent capable of having a biological effect" (page 10, lines 1-2). The instant specification does not specifically define "scaffold unit". When the generic claims (e.g. claim 15) are compared with the subgeneric claims (e.g. claim 29 {not under examination, non-elected species, see paragraphs 10-11}) and/or the elected species, it is clear that moieties such as phenyl and –OH fall within the definition of "pharmacophore". See for example, the elected species (Response, page 2, top), which is the following structure (shown in part):



as compared to the "polypharmacophore" defined in claims 29-42 comprising the formula (III) {and similarly (IIIA)} where "at least two of A, B or C comprise a pharmacophore":



See also rejections under 35 USC 112, first and second paragraphs above.

Thus, for the purposes of this rejection, ***any*** compound that is comprised of three units is deemed to read on the claimed "polypharmacophore".

Moldt et al disclose compounds that read on the claimed "polypharmacophore" having a tropane ring as the "scaffold unit" and alkyl, phenyl and heterocycle moieties reading on the "pharmacophores". See Abstract and Examples of the patent, for example, especially Example 25 and patented

claim 8 where compounds are described having units comprising CH_3, substituted phenyl and substituted oxadiazole that would read on the claimed "pharmacophores".

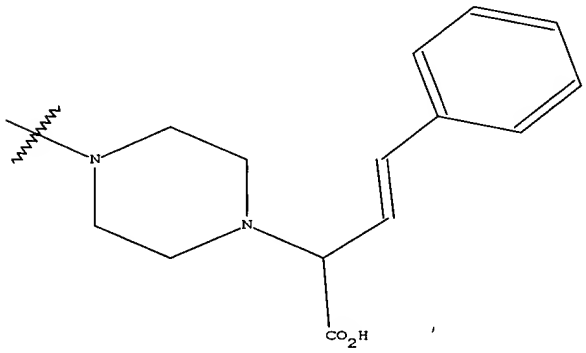
Moldt et al disclose pharmaceutical compositions of their compounds, see patented claim 9. This reads on the instant claim 43.

The above compounds read on the limitations found in claims 20 and 27 as the structures of the references read directly on the claimed "polypharmacophore". Note that a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Also, note that the reference discloses that their compounds have dopamine reuptake inhibiting activity (see column 1, line 45 through column 2, line 54).

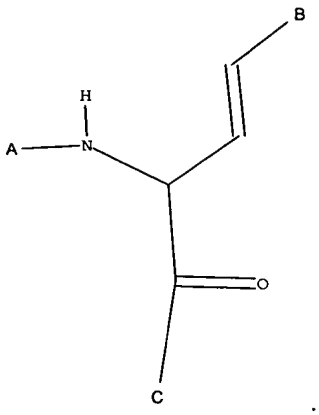
Moreover, with respect to the limitations in claims 17-19 and 24-26, the intended use recitations in these claims have not been given any patentable weight. See MPEP 2111.02: "... in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." The structures in Moldt et al are deemed to be capable of performing the intended uses recited in claims 17-19 and 24-26.

25. Claims 15-20, 22-27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Cordi et al (US 5,208,260; on PTO-1449).

The instant claims are drawn to a "polypharmacophore", which is made of "pharmacophores" attached to a "scaffold unit". The specification only defines a pharmacophore as an "agent capable of having a biological effect" (page 10, lines 1-2). The instant specification does not specifically define "scaffold unit". When the generic claims (e.g. claim 15) are compared with the subgeneric claims (e.g. claim 29 {not under examination, non-elected species, see paragraphs 10-11}) and/or the elected species, it is clear that moieties such as phenyl and –OH fall within the definition of "pharmacophore". See for example, the elected species (Response, page 2, top), which is the following structure (shown in part):



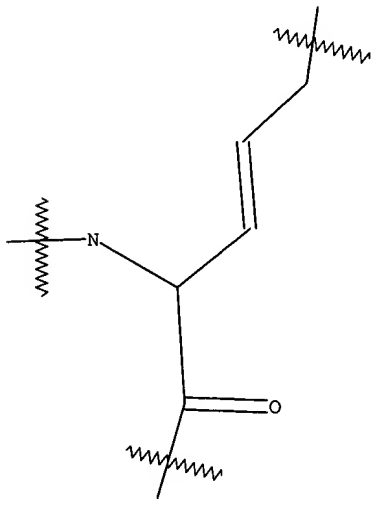
as compared to the "polypharmacophore" defined in claims 29-42 comprising the formula (III) {and similarly (IIIA)} where "at least two of A, B or C comprise a pharmacophore":



See also rejections under 35 USC 112, first and second paragraphs above.

Thus, for the purposes of this rejection, ***any*** compound that is comprised of three units is deemed to read on the claimed "polypharmacophore".

Cordi et al disclose compounds that read on the claimed "polypharmacophore" having a the following structure as the "scaffold unit" (see Abstract):



and having various moieties such as substituted/unsubstituted acyl, ester, alkyl and/or phenyl reading on the "pharmacophores". See for example, Example 136

of the patent where a compound is described having units comprising C_6H_5-C(O), t-butyl ester and alkyl that would read on the claimed "pharmacophores".

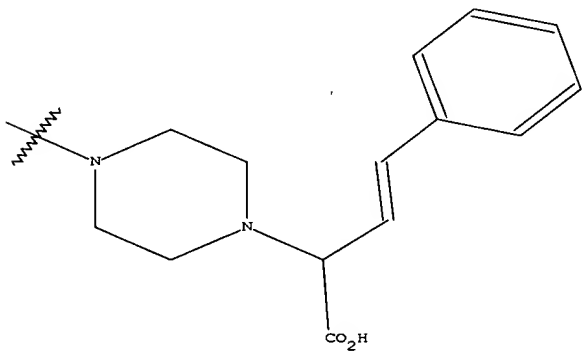
Cordi et al disclose pharmaceutical compositions of their compounds; see column 12, line 22 through column 13, line 2. This reads on the instant claim 43.

The above compounds read on the limitations found in claims 20 and 27 as the structures of the references read directly on the claimed "polypharmacophore". Note that a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Also, note that the reference discloses that their compounds can be used to treat diseases/conditions such as Alzheimer's and learning deficit (see column 11, lines 51-63, for example).

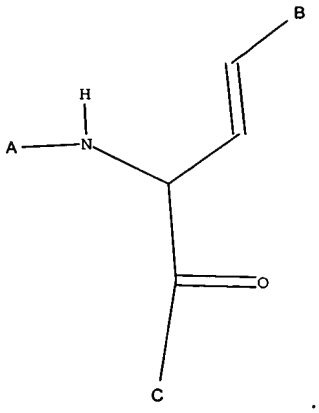
Moreover, with respect to the limitations in claims 17-19 and 24-26, the intended use recitations in these claims have not been given any patentable weight. See MPEP 2111.02: "... in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." The structures in Cordi et al are deemed to be capable of performing the intended uses recited in claims 17-19 and 24-26.

26. Claims 15-20, 22-27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeitlin et al (US 5,733,756).

The instant claims are drawn to a "polypharmacophore", which is made of "pharmacophores" attached to a "scaffold unit". The specification only defines a pharmacophore as an "agent capable of having a biological effect" (page 10, lines 1-2). The instant specification does not specifically define "scaffold unit". When the generic claims (e.g. claim 15) are compared with the subgeneric claims (e.g. claim 29 {not under examination, non-elected species, see paragraphs 10-11}) and/or the elected species, it is clear that moieties such as phenyl and –OH fall within the definition of "pharmacophore". See for example, the elected species (Response, page 2, top), which is the following structure (shown in part):



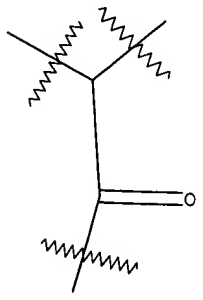
as compared to the "polypharmacophore" defined in claims 29-42 comprising the formula (III) {and similarly (IIIA)} where "at least two of A, B or C comprise a pharmacophore":



See also rejections under 35 USC 112, first and second paragraphs above.

Thus, for the purposes of this rejection, ***any*** compound that is comprised of three units is deemed to read on the claimed "polypharmacophore".

Zeitlin et al disclose compounds that read on the claimed "polypharmacophore" having a the following structure as the "scaffold unit" (see Abstract):



and having the moieties of phenyl, methyl ester and heterocycle reading on the "pharmacophores". See for example, the compound in column 1, lines 20-34 of the patent.

Zeitlin et al disclose testing of their compounds in biological liquids (column 4, lines 45-54) and use of their compounds for treatment (column 1, lines

34-37) reading on pharmaceutical compositions. This reads on the instant claim 43.

The above compounds read on the limitations found in claims 20 and 27 as the structures of the references read directly on the claimed "polypharmacophore". Note that a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Also, note that the reference discloses that their compounds can be used to treat Attention Deficit Disorder (see column 1, lines 34-37, for example).

Moreover, with respect to the limitations in claims 17-19 and 24-26, the intended use recitations in these claims have not been given any patentable weight. See MPEP 2111.02: "... in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." The structures in Zeitlin et al are deemed to be capable of performing the intended uses recited in claims 17-19 and 24-26.

Claim Rejections - 35 USC § 102/103

27. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

30. Claims 16 and 23 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Gootjes (US 4,202,896; Gootjes 1) or Gootjes (US 4,265,894; Gootjes 2) or Moldt et al (US 5,369,113) or Cordi et al (US 5,208,260; on PTO-1449) or Zeitlin et al (US 5,733,756).

Each of the above references are deemed to disclose a "polypharmacophore" reading directly on the claimed invention. See above for the discussion of the disclosure of each reference.

In the alternative, although none of the references specifically discloses the exact same procedure for synthesizing the scaffold as instantly claimed, it would be obvious to one of ordinary skill to do so as this was an established method for making such chemical moieties at the time of the invention.

The above-described compounds of each of the references meet all of the limitations of the "polypharmacophore" of the instant claims except for the product-by-process limitations and would either anticipate or render obvious the claimed compound. "[E]ven though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Also please see MPEP 2112. The examiner respectfully points out that since the claim is drawn to a "polypharmacophore", but this product is defined as a product-by-process in claims 16 and 23, that ***any*** compound reading on the instant "polypharmacophore" reads on this product. The process by which the claimed "scaffold unit" of the "polypharmacophore" is made does not appear to

lend patentable weight to the claimed invention. One of ordinary skill would expect the compound to be the same no matter how it was synthesized.

Status of Claims/Conclusion

31. No claims are allowed.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

MAURIE GARCIA, PH.D
PATENT EXAMINER

Maurie Garcia Baker, Ph.D.
July 19, 2002